This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

Questions and Answers for the FDA Reviewer Guidance: Labeling Reuseable Medical Devices For Reprocessing In Health Care Facilities

These answers have been prepared by Infection Control Devices Branch to assist with questions that may arise from implementation of this guidance. Please notify Dr. Chiu Lin of the Infection Control Devices Branch if there are additional questions about this guidance.

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REUSE OF MEDICAL DEVICES : QUESTIONS / ANSWERS

CONSUMER OR HEALTHCARE FACILITY

1.Q: Does this Reuse Guidance apply directly to the end user of a reusable medical device?

A: No, not directly. The guidance document is primarily intended as a guide to FDA reviewers and manufacturers. It describes criteria for product evaluation and guidance to the manufacturer of a reusable device on how to validate labeling instructions for reprocessing a reusable device. The guidance includes information that will be of interest to end users. Therefore, we would encourage end users to obtain a copy of the guidance.

2.Q: Does this Guidance Document apply to (1) reuse of single use devices, or (2) when a single use device package is inadvertently opened?

A: No, the Reusable Medical Devices Guidance only applies to medical devices labeled for reuse and to the initial processing of single-use only devices that are supplied non-sterile. FDA guidance is being developed on reuse of single use devices.

3.Q: Can a different method of reprocessing be substituted for the method recommended by the manufacturer?

A: FDA recommends that the manufacturer's labeling instructions be followed. If the end user wishes to use a method of reprocessing different from that recommended by the manufacturer, there is no assurance that the process will be satisfactory. The end user assumes responsibility for validating a method different from that recommended by the manufacturer.

In some cases the labeling for a reusable device that was marketed prior to the FDA initiative on reuse labeling may not be up-to-date in terms of reprocessing information. In that case, the user may find it necessary to supplement the given instructions with additional steps that are consistent with current infection control practices. FDA encourages manufacturers of older devices to upgrade labeling that is not current.

4. **Q:** Can an end user utilize a protective barrier device to eliminate reprocessing steps by reducing the level of gross contamination during use?

A: FDA recommends that the end user follow the manufacturer's instructions for both the barrier and the reusable device. Reusable device labeling may include recommendations on the use of barrier products to minimize the reprocessing steps that otherwise would be needed. While barriers may minimize contamination, their use may not eliminate all opportunities for the reusable device to become contaminated. For this reason even if a barrier product is used with a device there should still be a recommended method of cleaning and disinfection, albeit modified to reflect the use of a barrier. As noted in question #1, if the end user employs an alternative method from that recommended by the manufacturer, they must validate the alternative method. If a barrier device is used, the instructions for utilizing the barrier and reprocessing the device must be carefully followed.

5. **Q:** Can a reusable device be used past its recommended reuse life?

A: The manufacturer's recommended reuse life, if one is stated, should be followed. If the end user uses the device past the recommended reuse life, the end user assumes responsibility for such continued use of the device.

6. **Q:** If the reuse instructions recommended by the manufacturer differ from recommended practices set by professional societies or the healthcare facility, what should one do?

A: If the labeling for the device is current in terms of FDA's initiative on reusable devices then it should be followed. As noted above, older devices may not have current labeling and so professional practices and facility policy may be an important adjunct. When there are significant conflicts between labeling and recommended practices or institutional policy, the end user must reconcile these differences with the device manufacturer.

7. **Q:** If there are questions concerning reprocessing procedures to whom do I go for help?

A: The manufacturer of the reusable device is the appropriate contact for further questions.

ODE Reviewer

1.Q: Are there criteria for evaluating the validity of a reuse protocol the manufacturer has used?

A: Currently there are no specific criteria or standards for evaluating the validation of reprocessing instructions for the reuse protocol. The guidance on labeling of reusable devices includes a general scheme for validation studies and references to information on validation of procedures. The Infection Control Devices Branch is working with standard setting organizations like AAMI to develop specific criteria.

2.Q: Can I ask the manufacturer for validation data in my 510(k) review? What about PMA reviews or IDEs?

A: Requests for in depth evaluation of qualification tests conducted as part of the validation for 510(k) submissions are not necessarily part of the review unless: 1) recommended in a device specific guidance, 2) directed by management on a case by case basis, or 3) when requested by the Office of Compliance.

The validation of reprocessing instructions for a PMA device will be reviewed in the same manner as other manufacturing and control data. Refer to the Blue Book policy for the specifics. For PMAs the manufacturer will need to submit data documenting the safety and efficacy of the proposed reprocessing instructions. The review of an IDE can include evaluation of a summary of the validation study.

3.Q: Do manufacturers have to submit data from their validation study or is a certification of the study acceptable?

A: For a 510(k), the manufacturers can submit a certification of the validation study unless a device specific guidance requires actual validation data. PMA reviews will continue to require the actual validation data.

4.Q: Are draft standards from a standard setting organization for cleaning and disinfection acceptable as a means for validation?

A: Since draft standards are still in process they may have limited utility or scientific merit. Until tests in draft standards are validated through round robin testing, and the standards are finalized, they should not be relied upon solely as a basis for product validation.

5.Q: What are the acceptable infection control outcomes that an end user is attempting to achieve when reprocessing a reusable device?

A: The goal when reprocessing a reusable device generally depends on the device's intended use. A critical device is a medical device that is intended to enter a normally sterile environment. It must be thoroughly cleaned and sterilized between patient use. A semicritical device is a medical device that is intended to come in contact with mucous membranes and does not ordinarily penetrate body surfaces. It must be thoroughly cleaned and subjected to a germicidal process with a broad spectrum of activity. Sterilization of a semicritical device is desirable, but high level disinfection is acceptable when sterilization is not feasible. A noncritical device is a medical device that comes into contact with intact skin. The device must be thoroughly cleaned. If there is a concern regarding transmission of pathogens, then an intermediate or low-level disinfectant should be used. In some cases thorough cleaning alone, is acceptable.

6.Q: Are the manufacturers aware of this guidance?

A: Yes, it was formally announced and made available for comment in FR Vol 60 No.115 (June 15, 1995) and has been made final as of April 1996. The content of the document was presented at a national conference of the Association for the Advancement of Medical Instrumentation..

7.Q: Can a 510(k) be placed on hold, or found NSE for lack of reprocessing instructions and/or a statement of validation?

A: Yes.

8.Q: If 510(k) reviews don't require the submission of the validation data, how can a reviewer know that the testing of the reprocessing instructions is adequate?

A: Evaluation of preproduction design validation activities is primarily the responsibility of the Office of Compliance and the field staff under the good manufacturing practices regulations. Except as specified in the guidance, the applicant must supply documentation in the 510(k) that the validation has occurred or will occur. Data from labeling validation must be available for inspection by the field staff, if requested.

9.Q: Does the manufacturer have to validate reprocessing instructions that are based upon recommended guidance developed by a related professional practice group?

A: Yes. The manufacturer is required to validate any reprocessing methods they recommend in their labeling or promotional materials.

Manufacturer

1.Q: I have a device which is cleared for single use. If I want to market it as reusable what is required? If I want to market a reusable device as single use what do I do?

A: In order to market a single use device as reusable, a new 510(k) is required since there is a potential impact on the safety and effectiveness of the device. The 510(k) must include the appropriate validation studies that demonstrate that it is compatible for reuse. On the other hand a 510(k) may not be needed when changing a reusable device to single use only. The applicant must assess the impact of the change on its safety and effectiveness.

2.Q: If my device has been cleared for marketing as a reusable device, do I have to file a new 510(k) to conform with the Reuse Guidance?

A: No, the only requirement would be to have validation data on file.

3.Q: Don't Hospitals have their own reprocessing standards? Why is it necessary to recommend a processing procedure?

A: The general reprocessing standards in a healthcare facility may not be appropriate for all devices. Since a device manufacturer has the best knowledge of its device, it is important for the manufacturer to recommend a properly validated procedure for the user to follow.

4.Q: Do I need to validate each step of the validation process?

A: The cleaning and disinfection or sterilization steps must be validated separately since the expected outcomes differ. Cleaning is removal of visible contamination, while disinfection or sterilization is the killing of microorganisms. For specific details consult the references in Appendix 8 of the Reuse Guidance.

5.**Q:** What kind of endpoint can I use to validate cleaning, disinfection and/or sterilization steps?

A: The definition of cleaning is the removal of visible contamination. The manufacturer should design the test to demonstrate that a soiled device can be rendered free from contamination to the degree that the device is visibly free of soil. The accepted endpoints for disinfection depend on the degree of disinfection that is recommended. There are standards on validating sterilization processes which discuss how to verify the required sterility assurance level. Please refer to the following guidance documents for further information: Guidance on Premarket Notification [510(k)] Submissions for Sterilizers Intended for Use in Healthcare Facilities or Guidance on the Content and Format of Premarket Notification [510(k)] for Liquid Chemical Germicides.

6.**Q:** Are draft standards from standard setting organizations for cleaning and disinfection acceptable as a means of validation?

A: Because draft standards have not been validated and are subject to change before finalization, the manufacturer must be sensitive to the fact that the draft procedures may not be scientifically sound and therefore are not acceptable as a reference. However, if you have validated the process referred to for your device, you may describe the method in your labeling.

LABELING REUSABLE MEDICAL DEVICES FOR REPROCESSING IN HEALTH CARE FACILITIES: FDA REVIEWER GUIDANCE

OFFICE OF DEVICE EVALUATION

APRIL 1996

Scope

This guidance provides recommendations regarding the content of reuse instructions in labeling for reusable medical devices. The recommendations are also applicable to the initial processing of single-use only and reusable devices that are supplied nonsterile, and reprocessing of certain sterile, single-use only implantable devices if they become contaminated before implantation (e.g., orthopedic implants).

The guidance is primarily directed to FDA personnel who are responsible for the evaluation of premarket notification submissions [510(k)s], premarket approval applications (PMAs), and investigational device exemptions applications (IDEs). The guidance will also assist persons preparing 510(k)s, PMAs, and IDEs for submission to FDA.

Under FDA labeling regulations, 21 CFR 801, a device must have adequate directions for use, which include instructions on preparing a device for use. Instructions on how to reprocess (i.e., clean, and disinfect or sterilize) a reusable device are important steps in preparing a device for the next patient.

This document is not intended to be an in-depth guidance on device design and testing factors related to infection control. However, it is essential that the manufacturer consider infection control requirements during product design and testing to facilitate cleaning, and sterilization or disinfection, if necessary. Design and testing factors are addressed in device-specific FDA guidance, and FDA good manufacturing practices (GMPs) guidance.

FDA staff and persons preparing submissions should also refer to the Technical Information Report (TIR) developed by the Association for the Advancement of Medical Instrumentation (AAMI) entitled Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers, AAMI TIR No.12-1994. The AAMI TIR provides comprehensive technical information for manufacturers, and user perspectives on this topic. This FDA reviewer guidance complements the AAMI TIR.

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A. Overview of Device Reprocessing

The following is a brief overview of how reusable medical devices are reprocessed in health care facilities. Please refer to the AAMI TIR for an expanded description of device reprocessing. Supplemental information on reprocessing of some specific devices, such as endoscopes, is available from FDA and professional associations.

Preparing reusable devices for the next patient can be challenging for health care facilities. Unlike bioburden-based manufacturing sterilization processes, the health care workers responsible for reprocessing reusable devices do not know the amount and resistance of contamination on the devices to be reprocessed. The device labeling, professional practices, and institutional infection control procedures help guide the persons who are responsible for reprocessing devices. Institutional device reprocessing should occur in facilities that are adequately designed, equipped, monitored, and staffed by trained personnel.

Principles of infection control require that all contaminated devices be correctly and safely handled by health care personnel, and that the reusable devices be adequately reprocessed. Proper handling and reprocessing of reusable devices for the next patient requires several steps. Diligent execution of all steps is extremely important. The general reprocessing steps are as follows:

1. Reprocessing begins at the point of use. Contaminated reusable devices are segregated from waste. Any protective covers that were used to minimize device contamination are discarded. Contaminated devices may be wiped clean of visible soil at the point of use. The reusable devices that require reprocessing at a decontamination and sterilization work area are then properly contained.

2. Contained, soiled devices are transported to a decontamination and sterilization work area.

3. The devices are decontaminated. Decontamination is a process that is intended only to render the device safe for handling by health care workers. A decontaminated device may not necessarily be suitable for patient use.

    a. The soiled devices are disassembled, when possible, to facilitate the decontamination process of cleaning and, if necessary, disinfection or sterilization.

    b. The devices are thoroughly cleaned with a compatible detergent then rinsed to remove residues. Other accessories and procedures, such as enzyme cleaners and

ultrasound baths, may also be used to remove organic matter from the devices. Careful cleaning is crucial since it not only can remove most contamination, it helps ensure the effectiveness of any subsequent microbicidal process. As a rule, a reusable device should be designed so that it can be adequately cleaned. If a device cannot be adequately cleaned, any subsequent disinfection or sterilization process may not achieve the desired result.

c. After the reusable devices are cleaned, they may require additional microbicidal steps, including either a disinfection or sterilization process, to render them safe for handling. For example, extra microbicidal steps may be appropriate for devices that institutions assume are contaminated with a virulent pathogen, e.g., Mycobacterium tuberculosis.

4. Devices that have been decontaminated are then segregated into those devices that may be returned directly to service, as is, and those that still require a terminal microbicidal process, e.g., sterilization.

5. If required, a terminal process is completed. Devices are returned to service.

B. Responsibilities Regarding Reusable Medical Device Labeling

FDA agrees with the AAMI Reuse TIR that the responsibility for safe and effective reprocessing of medical devices rests with BOTH the manufacturer of the reusable medical device and the user of the device. Manufacturers of reusable medical devices are responsible for supporting the claim of reuse with adequate labeling. The labeling must provide sufficient instructions on how to prepare the device for the next patient. The manufacturer is also responsible for documentation of tests which show that the instructions are adequate and can be reasonably executed by the user. The users are responsible for ensuring that they have the facilities and equipment to execute the instructions, and that the instructions are followed.

C. Criteria for Reprocessing Instructions

Introduction

This part describes SEVEN CRITERIA for evaluation by the FDA reviewer. If the labeling is deficient based on any relevant criterion, then the FDA reviewer should inform the applicant of the deficiency. The applicant must submit either correct labeling, or an adequate justification, with supporting documentation, why they believe the labeling is adequate, in a manner consistent with Office of Device Evaluation Blue Book policy on communication with industry. The seven criteria are reduced to a reviewer checklist in Part G on page 14.

The applicant must provide reasonable grounds for omission of reprocessing information (per 21 CFR 801.109(c)) for prescription devices. One example is that there are "commonly understood" infection control practices for solid, single piece stainless steel surgical instruments. Cleaning and steam sterilization of these devices is relatively standard practice. The ODE reviewer should carefully evaluate any request for an omission along with the supporting documentation. If FDA accepts the omission, the reviewer should inform the applicant that the ability to reprocess the device according to the established, common practices must still be qualified and documented by the applicant.

Note that labeling of several marketed reusable devices direct the user to reprocess the device according to "hospital procedures." Unless the reusable device meets the criteria for labeling omission noted above, this labeling statement alone is unacceptable because sufficient standard procedures do not exist for many devices.

Additional Factors to Consider

Since this guidance is not specific to any particular device, the ODE reviewer should rely upon the following factors, in addition to the seven criteria detailed beginning on the next page, to determine whether the labeling is adequate:

1. device specific FDA guidance,

2. applicable regulations, such as the labeling exemption for surgical instruments under 21 CFR 801.109(b) or device specific labeling requirements in Part 801, Subpart H,

3. labeling for other similar legally marketed devices (see Section D for limitations),

4. consistency across a product line,

5. the reviewer's experience in the product area,

6. infection control problems associated with the device noted in the FDA device problem reporting system, the literature, FDA safety alerts, etc.,

7. consultation with knowledgeable, authorized people, such as FDA staff, special government employees, and other government experts,

8. specific patient and user risks posed by the device, and

9. relevant professional, government, and industry infection control guidance, guidelines and standards.

The Seven Criteria

1. In general, **labeling for a reusable device that contacts the patient in some manner must include reprocessing instructions.** Care instructions for devices that do not typically contact patients are recommended.

   AND

   The labeling for a patient contact device sold nonsterile, whether or not it is reusable, must include initial instructions on how to make the device patient ready.

2. All reprocessing instructions should include **a statement that the device must be thoroughly cleaned.**

   Thorough cleaning is only the first step required for effective reprocessing, but it may be all that is necessary, depending on the intended use of the device. The details of the cleaning procedure may vary depending on the complexity of the device.

   Device labeling may include directions regarding the use of protective covers to minimize the extent of cleaning and further reprocessing needed before device reuse. All protective covers have not been evaluated by FDA according to consistent criteria. As a result, the utility of protective covers may vary from product to product. When protective covers are mentioned in labeling for reusable devices, the labeling should refer to protective covers with claimed liquid and microbial barrier properties. In turn, these claims, and other important factors, must be validated by the protective cover manufacturer and assessed under the 510(k) process for the protective covers.

   The cleaning step may be included in labeling as part of a

decontamination regimen. Since decontamination addresses user safety and not necessarily patient safety it is important for the manufacturer to evaluate the rigor of the cleaning process in terms of how adequate the process will be in eliminating visible soil from the device to make the device patient ready, thus making any required terminal process more effective.

3. **The instructions must indicate the appropriate microbicidal process for the device.**

   The labeling should indicate either:

   STERILIZATION

   OR

   HIGH, INTERMEDIATE, OR LOW LEVEL DISINFECTION

   Refer to the Processing Triage in Appendices 1 and 2 for assistance in determining the appropriate microbicidal process. The reprocessing instruction in the labeling must be consistent with the standard of care expressed by government agencies and relevant professional organizations. For example, FDA currently expects that labeling for flexible endoscopes used in the GI and respiratory tracts will provide both sterilization and high level disinfection procedures.

   FDA will not accept less than the minimum acceptable level of reprocessing, as described in Appendices 1 and 2. The reviewer should refer any deviations to division staff with infection control experience or to the Chief, Infection Control Devices Branch, Division of Dental, Infection Control, and General Hospital Use Devices for a consultation.

4. **The process must be feasible considering the intended location of reprocessing (e.g., health care facility or home use).**

   Persons reprocessing reusable devices must have the ability to carry out the reprocessing steps. Some types of sterilizers, such as radiation sterilization, are used only in manufacturing facilities. Steam sterilization is the most common method of sterilization used in health care facilities. Chemical vapor, ethylene oxide, gas/plasma and liquid chemical sterilizers are also found in many facilities. Dry heat sterilizers are less common in some environments.

   Some simple reprocessing of devices takes place in the

home, either by trained personnel or lay persons. For example, some medical equipment used commonly in the home setting can be cleaned, surface disinfected, if needed, and serviced on site. Also, reusable contact lenses, which are common devices, are cleaned, disinfected, and rinsed by users.

5. **The instructions must be understandable.**

Instructions must be clear, grammatically correct, legible, and in logical order from the initial processing step through to the terminal processing step (e.g., preprocessing, cleaning, rinsing, disinfection or sterilization, final rinsing after disinfection or liquid chemical sterilization, and post-process handling).

6. **The instructions must be comprehensive.**

Comprehensive instructions enable the person responsible for reprocessing the device to understand precisely how to execute the reprocessing regimen safely and effectively. There may be several acceptable formats for instructions. The ODE reviewer should concentrate on the sequence of steps and content of each step. Instruction must at least be in English. Inclusion of duplicate instructions in other languages are solely at the discretion of the manufacturer.

The elements of comprehensive reprocessing instructions are listed below. Comments related to the qualification of specific elements are noted in brackets []. The ODE reviewer must use judgement to determine if an element applies to the device under review.

a. Special Accessories: The instructions should describe any special cleaning, and sterilization or disinfection accessories that are required or recommended (e.g., special tools, trays, test kits, specific types of sterilization wraps or containers, protective covers, etc.).

b. Special Pre-processing Handling: Special preprocessing handling requirements should be described, as needed (e.g., for items contaminated with protein material, prevention of drying prior to cleaning will facilitate cleaning).

c. Disassembly/Reassembly: If the device consists of more than one removable part, then disassembly/reassembly instructions must be included.

d. Method of Cleaning: The labeling should recommend a method of cleaning. The method listed may be manual or mechanical (e.g., washer, washer/disinfector, ultrasonic washer, etc.).

[The cleaning qualification should determine the parameters for cleaning, and the labeling should describe the requirements (e.g., water quality, time-at-temperature, etc.). If a cleaning method is not specified, then the manufacturer must qualify a representative sample of commonly used methods of cleaning.]

e. Cleaning/Lubricating Agents: The instructions should recommend compatible cleaning and lubricating agents or a class of agents (e.g., anionic detergents, detergent/disinfectants, enzymatic detergents, water soluble lubricants, etc.). The labeling for the reusable device should refer to the cleaning and lubricating agent labeling for preparation and use instructions of those agents.

[If a specific agent or class of agents is not identified, then the cleaning qualification should include a representative sample of commonly used products.

Qualification tests may determine that additional instructions are needed when using cleaning and lubricating agents. If the additional instructions significantly impact the intended use or conditions of use of the cleaning/lubricating agents (e.g., change in process time, temperature, material compatibility, etc.), then the manufacturer must qualify the safety and effectiveness of the agents under the modified conditions of use.]

f. Rinsing: Specific directions for adequate rinsing after cleaning and any liquid chemical disinfection or sterilization, should be recommended including the type and quality of rinse water, volume, and duration of rinse. Rinsing may be manual or mechanical. If the rinsing instructions in the cleaning and disinfecting/sterilizing product's labeling are sufficient then reusable device labeling may refer to those instructions.

[Rinsing instructions must be qualified to show that residual cleaning agents are removed to a level that will not interfere with subsequent reprocessing steps, and liquid chemical germicides

are removed to a level that is nontoxic.]

g. Method of Disinfection or Sterilization: When applicable, labeling should specify at least one qualified method for disinfection or sterilization including specific parameters (e.g., cycle parameters, aeration, if applicable, specific liquid chemical germicide, orientation or positioning of the device in the sterilizer, etc.). If the labeling lists a generic type of sterilization or disinfection process, e.g., "steam sterilization," with no specifics on cycle parameters, then the applicant must qualify all forms of the listed generic method.

[Care must be exercised by manufacturers of reusable devices to ensure that sterilization processes listed in labeling are safe and effective for their specific device. Microbicidal processes are not interchangeable. Each type of process has its advantages and limitations. For example, heat labile devices must be sterilized by a non-thermal process, e.g., vapor, gas/plasma, or liquid chemical sterilant. A device may require a particular mode of steam sterilization. Some methods are complex (e.g., EtO) and specific directions are essential.]

h. Special Post-process Handling: Special post-processing procedures should be recommended, as needed, in order to eliminate or minimize recontamination before reuse. A recommended post-process aeration time must be provided if labeling recommends EtO sterilization.

i. Reuse Life: The labeling should tell the user, based upon testing, how many times the product can be reused, or provide a mechanism to ascertain that the device is still within specifications. For example, the labeling for reusable devices (1) state the maximum number of reuses and provide a tracking method, e.g., the fabric grid provided for reusable surgical gowns, (2) identify a performance test that must be passed prior to reuse, or have an automatic precheck function, or (3) describe unacceptable deterioration, such as corrosion, discoloration, etc..

j. Special Warnings and Precautions: Special warnings or precautions regarding the reprocessing procedure should be described, when warranted. These may relate to user safety, or emphasize conditions that may significantly impact upon the effectiveness of reprocessing or the performance

of the device.

k. Lay Use: Devices that are intended to be maintained by a patient or lay health care provider must have reprocessing instructions which are understandable to a lay person, and which can be done at home. The ODE reviewer should direct the manufacturer to the Division of Small Manufacturers Assistance for FDA guidance on home use labeling if there are deficiencies.

l. Reference to Guidance Documents or to Labeling of Accessory Devices: The device labeling may refer to professional practices/guidance or to labeling of accessory devices used in reprocessing (e.g., washers, washer/disinfectors, automated endoscope reprocessors).

For example, reference to guidance by the Association of Operating Room Nurses, The Centers for Disease Control and Prevention, the Association for Practitioners in Infection Control, Inc., etc., may substitute for reiteration of equivalent directions. The manufacturer must still validate the instructions regardless of the source of the instructions.

Reference to labeling of other devices used in reprocessing is acceptable provided labeling statements are consistent and complement one another. For instance, labeling for an endoscope may refer, in part, to endoscope washer labeling for certain details on scope reprocessing (e.g., placement in chamber).

m. Telephone Number to Request Information: The instructions should include a telephone number to obtain additional information on the device, including questions on infection control procedures.

n. Statement on the Need for the User to Qualify Deviations from the Recommended Method: The labeling may advise that it is the users' responsibility to qualify any deviations from the recommended method of processing, and may state appropriate disclaimers if there are deviations.

7. **The instructions must include only devices and accessories that are legally marketed.**

Many products used in reprocessing reusable devices are currently subject to FDA premarket clearance. These include

all sterilizers used in health care facilities, as well as liquid chemical sterilants and disinfectants intended for use on medical devices. General lubricants, presoaks, enzyme cleaners, and detergents and glassware washers are exempt from premarket clearance as general purpose articles.

Within 45 days of the release of this document the Infection Control Devices Branch will establish and maintain a LAN file which will list the legally marketed liquid chemical sterilants and high level disinfectants, until further notice. Numerous intermediate and low level disinfectants have been cleared.

D. Predicate Device Labeling

When evaluating a 510(k) the ODE reviewer compares the labeling for the claimed legally marketed equivalent device to the labeling for the new device. The reviewer identifies differences and assesses the impact of the differences on equivalence. Reprocessing instructions for some legally marketed reusable devices may not be consistent with state-of-the-art infection control procedures, therefore, the reviewer cannot necessarily rely on the predicate labeling as a model for the new device in regard to infection control instructions. In the interest of public health, reprocessing instructions for the new device must be consistent with state-of-the-art infection control procedures.

If an ODE reviewer, in agreement with their management, finds that the 510(k) applicant is relying on predicate labeling that could be a public health concern in regard to infection control issues then he/she should 1) recommend that the applicant update the labeling of the new device in accordance with this guidance; and 2) send a memo to the Director, Office of Compliance (OC) through channels, informing OC of the deficient instructions for the predicate device. If the applicant does not agree with the recommended update in labeling the burden is on the applicant to justify, with supporting documentation, why they believe the labeling is consistent with state-of-the-art infection control practices.

E. Documentation of Validation of Reprocessing Instructions

The 510(k), PMA, or IDE must include the following documentation on the validation of the reprocessing instructions:

1. **A 510(k) must include a statement on the status of the validation.**
   A statement should be included in the 510(k) that is signed by the applicant, their agent, or other legally responsible individual attesting to the status of the validation. Two

examples of statements are provided below.

Statement 1 may be submitted for a completed validation, where the labeling in the 510(k) is based upon the results of the qualification tests.

Statement 2 is ONLY for the following situations: (1) the validation has not been completed, and there is either a device specific industry standard, specific regulatory guidance document, or a relevant standard on validation of the reprocessing instructions that the applicant will meet (see Option 1); OR (2) the manufacturer believes that the device is virtually identical, from an infection control perspective, to other devices for which the manufacturer has previously validated the reprocessing instructions, and the prior validation has been subject to GMP inspection (see Option 2).

STATEMENT 1, VALIDATION COMPLETED:
"The instructions for reprocessing the device have been validated according to [describe the published method or standard that is the basis for the validation]. I have enclosed a summary of the method of validation [when the basis is other than a published method or standard]. The complete validation is on record at [location] and available for inspection, and it will be supplied to FDA upon request. The validation includes protocols, specifications, pass/fail criteria, results, and procedures which describe when the instructions must be requalified (e.g., if the device is modified)."

OR

STATEMENT 2, OPTION 1, VALIDATION NOT COMPLETED:
"The instructions for reprocessing the device will be validated before the device is marketed according to [describe the published method or standard that is the basis for the validation]. I have enclosed a summary of the method [when the basis is other than a published method or standard]. The validation of the reprocessing instructions and the final labeling will be on record at [location] and available for inspection, and it will be supplied to FDA upon request. The validation will include protocols, specifications, pass/fail criteria, results, and procedures describing when the instructions must be requalified (e.g., if the device is modified)."